TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
04PCT0001		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/017542	18.11.2004	21.11.2003
International Patent Classification (IPC) or national classification and IPC		
C12Q1/68, C12N15/09		
Applicant		
MIURA, Norimasa		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))
      _____ , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

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International application No.
PCT/JP2004/017542

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1,2 ( )

because:

☒ the said international application, or the said claims Nos. 1,2
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matter of claims 1 and 2 pertains to diagnostic methods to be practiced in the human body.

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1,2
are so unclear that no meaningful opinion could be formed (*specify*):

Whether the invention set forth in claims 1 and 2 is directed to a method of detecting cancer or method of diagnosing cancer from a blood sample in accordance with the RT-PCR method is unclear. With respect to the unclear description, search has been carried out interpreting it as meaning the "method of detecting cancer".

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1,2 ( )

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
☐ has not been furnished
☐ does not comply with the standard

the computer readable form
☐ has not been furnished
☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☒ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted the claims nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

   ☐ complied with.

   ☒ not complied with for the following reasons:

The technical matter common to claim 1 and claim 2 is a method of detecting a tumor marker gene through performing RT-PCR with respect to an RNA sample obtained from a body fluid. However, this common matter is publicly known as described in, for example, the following literature. Therefore, claim 1 and claim 2 cannot be stated as sharing a special technical feature, so that this invention group cannot be stated as being a group of inventions inked with each other so as to form a single general inventive concept.

Document: Clinical Cancer Research, October 2000, Vol. 6, pages 3823 to 3826

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1,2 ( )

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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1, 2	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1, 2	NO
Industrial applicability (IA)	Claims	1, 2	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: Chen X.Q. et al., "Telomerase RNA as a Detection Marker in Serum of Breast Cancer Patients", Clinical Cancer Research, October 2000, Vol. 6, No. 10, pages 3823-3826

Document 2: Funaki N. et al., "Quantitative Analysis of Alpha-Fetoprotein mRNA in Circulating Peripheral Blood of Patients With Hepatocellular and Alpha-Petoprotein-Producing Gastric Carcinomas", Life Science, 1998, Vol. 62, No. 21, pages 1973 to 1984

Document 3: Shin Takeda et al., "Gan no Bunshi Shindangaku - Kokomade Susunda Shinda/Chiryo eno Oyo - 5. Kangan ni okeru Idenshi Shindan no Genjo", Nichigai Kaishi, 2002, 103 (6), pages 472 to 475

Claim 1

Document 1 sets forth a method for detecting human telomerase (hTERT) genes by extracting mRNA from the blood serum of hepatic cancer patients and using the RT-PCR method, and a primer using said method.

It would therefore be easy for a person skilled in the art to conceive of a method wherein RNA is obtained

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

from blood serum and the human telomerase gene is detected by RT-PCR, in the light of document 1, and designing a primer using said method would be within the normal creative skill of a person skilled in the art.

Therefore the invention set forth in claim 1 does not involve an inventive step.

Claim 2

Documents 2 and 3 set forth a method wherein mRNA is extracted from the blood of hepatic cancer patients, and the AFP gene is extracted using the RT-PCR method. Document 2 also sets forth a primary for detecting the AFP gene.

That being the case, it would be easy for a person skilled in the art to conceive of a method of obtaining RNA from blood serum, and detecting the AFP gene using the RT-PCR method, and designing the primer for detecting the AFP gene used in this method would be within the normal creative skill of a person skilled in the art.

Therefore the invention set forth in claim 2 does not involve an inventive step.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Whether the invention set forth in claims 1 and 2 is directed to a method of detecting cancer or method of diagnosing cancer from a blood sample in accordance with the RT-PCR method is unclear.

With respect to the unclear description, search has been carried out interpreting it as meaning the "method of detecting cancer".

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☒ contained in the international application as filed

   ☐ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purposes of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

* *If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."*